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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/809,688

03/26/2004

Katsuhiko Yanagihara

31978-201641

8599

26694 7590 03/19/2007
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EXAMINER

TUNG, JOYCE

ART UNIT

PAPER NUMBER

1637

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/809,688

Applicant(s)

YANAGIHARA ET AL.

Examiner

Joyce Tung

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 32-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The applicant's response filed 12/19/06 to the Office action has been entered. Claims 1-36 are pending.

1. The rejections of claims 1-31 respectively under 35 U.S.C. 102(b) as being anticipated by Yanagihara et al. (PNAS, 2002, Vol. 99(17), pg. 11317-11321), under 35 U.S.C. 103(a) as being unpatentable over Yanagihara et al. (PNAS, 2002, Vol. 99(17), pg. 11317-11321), in view of Lampe et al. (6,368,830, issued April. 9, 2002), and under 35 U.S.C. 103(a) as being unpatentable over Yanagihara et al. (PNAS, 2002, Vol. 99(17), pg. 11317-11321), as applied to claims 1-11, 13-18, 20-21, and 23-27 above, and further in view of Jones et al. (2005/0037011, issued Feb. 17, 2005) are withdrawn because of the arguments.

NEW GROUND OF REJECTIONS

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-31 are vague and indefinite because the preamble is for detecting a mismatch in a test double stranded nucleic acid target, but the phrase "if the target comprises a mismatch" means that there might not be a mismatch in the target. It is unclear that the method is for detecting a mismatch in the target or the method is to detect transposition of Mu-end nucleic acid in the target. Clarification is required.

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b. Claims 1-31 are vague and indefinite because it is unclear what is the definition of the phrase "predominant site". Clarification is required.

c. Claims 1-31 are vague and indefinite because it is unclear what is encompassed by the phrase "under condition" for the Mu-end nucleic acid to transpose into the target at about the site of a mismatch. Clarification is required.

Allowable Subject Matter

4. Claims 1-31 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

5. The following is a statement of reasons for the indication of allowable subject matter:

Concerning claims 1-13, no prior art has been found teaching or suggesting a method for detecting a mismatch in a test double stranded nucleic acid target comprising the condition for the Mu-end nucleic acid to transpose into the target at about the site of mismatch, if the target comprises a mismatch.

Concerning claims 14-31, no prior art has been found teaching or suggesting a method for detecting the presence of a mutation or polymorphism in a nucleic acid of interest comprising the condition for the Mu-end nucleic acid to transpose into the target at about the site of mismatch, if the target comprises a mismatch.

The closest prior art is the reference of Savilahti et al. (The EMBO, 1995, Vol. 14(9), pg. 4893-4903). Savilahti et al. disclose the two chemical steps of phage Mu transpositional recombination, which satisfy the limitations of the claims (See pg. 4894, column 2, the first paragraph of Results and pg. 4895, fig 2) except that Savilahti et al. do not disclose the condition for the Mu-end nucleic acid to transpose into the target at about the site of mismatch, if the target

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comprises a mismatch. Therefore, the instant claims are allowable over the reference of Savilahti et al.


Summary


6. No claims are allowable.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung 
March 6, 2007


KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

3/13/07